AMERICAN ARBITRATION ASSOCIATION
ATLANTA, GEORGIA

EMORY UNIVERSITY and UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC.,	)	
Claimants and Counterclaim Respondents,	)	
v.	)	**Case No. 30 122 Y 00596 09**
PHARMASSET, INC.,	)	
Respondent and Counterclaim Claimant.	)	

AWARD OF ARBITRATORS

Claimants Emory University ("Emory") and University of Georgia Research Foundation, Inc. ("UGARF") (collectively, "Claimants") are parties to a license agreement dated January 8, 2004 (JX-2, hereinafter "the Agreement") with Respondent Pharmasset, Inc. ("Pharmasset").

Claimants filed a Demand for Arbitration and Relief on July 28, 2009, asserting that Pharmasset had failed to make royalty and milestone payments as required by the Agreement. Under the Agreement, Claimants granted to Pharmasset, *inter alia*, an exclusive right and license to make, have made, develop, use, import, offer for sale, and sell Licensed Products in the Field of Use anywhere in the world during the term of the Agreement. (*Id.* Art. 2.1.) Claimants alleged that certain Pharmasset compounds fell within the Licensed Compound Series under the Agreement. As such, Claimants contended that the use of those compounds by F. Hoffman-La Roche Ltd., Hoffman-La Roche, Inc. (collectively, "Roche"), and Pharmasset to treat HCV infection in clinical trials pursuant to a Collaboration Agreement dated October 29, 2004 ("the Roche Collaboration") fell within the definition of Licensed Products under the Agreement, and that the Roche Collaboration was a sublicense of the Agreement. Claimants also sought a declaration that Pharmasset had failed to identify a Lead Candidate, which gives Claimants grounds to terminate the Agreement pursuant to Article 12.2 of the Agreement.

On August 14, 2009, Pharmasset filed its Answering Statement, Affirmative Defenses and Counterclaims to Claimants' Demand. Pharmasset sought, *inter alia*, a declaration that claims 1, 2, 5, 7, and 9 of Licensed U.S. Patent No. 7,307,065 (JX-01, hereinafter "the '065 patent") are invalid and that claims 48, 49, 52, 54, 56, and 57 of Licensed U.S. Patent Application No. 12/510,083 (JX-10, hereinafter "the '083 application") are unpatentable.[1] Pharmasset also sought a declaration that Claimants breached the Agreement when they filed the '083 application without consulting Pharmasset, and an award of its fees, expenses, and attorneys' fees incurred in connection with the Arbitration.

Article 14 of the Agreement provides in relevant part that "[a]ny dispute related to this License Agreement shall be settled by arbitration . . . conducted under the Commercial Arbitration Rules of the American Arbitration Association." Over the course of this arbitration, the parties have submitted voluminous briefing, hundreds of exhibits, and extensive testimony.[2] Having carefully considered all of the parties' written submissions, testimony and evidence introduced at the Hearing held October 18–22, 2010, and independent case law research and analysis, and having been designated in accordance with Article 14 of the Agreement, and having been duly sworn, WE, THE UNDERSIGNED ARBITRATORS do hereby issue the following AWARD.

FACTUAL BACKGROUND

A. The Patents and Claims-At-Issue

Two Licensed Patents—the '065 patent and the '083 application—are at issue in these proceedings. Both the '065 patent and the '083 application are entitled simply "2'-Fluoronucleosides," and list eight inventors.[3] The '065 patent is a continuation of U.S. Patent No. 6,911,424, which is itself a continuation of U.S. Patent No. 6,348,587. The application

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[1] As used herein, the terms "patents-at-issue," "asserted patents," and/or "Licensed Patents at issue" refer collectively to the '065 patent and the '083 application. As used herein, the term "claims-at-issue" and/or "asserted claims" refers collectively to claims 1, 2, 5, 7, and 9 of the '065 patent and to claims 48, 49, 52, 54, 56, and 57 of the '083 application (as filed on July 27, 2009).

[2] Subsequently in this Award, reference is made to specific exhibits, portions of the patents-at-issue, and pages and lines of the Hearing Transcript. It should be understood that these citations are for illustration only and not as constituting the total record on point or the only evidence on which the Panel has relied.

[3] The named inventors are Raymond F. Schinazi, Dennis C. Liotta, Chung K. Chu, J. Jeffrey McAtee, Junxing Shi, Yongseok Choi, Kyeong Lee, and Joon H. Hong. Only Drs. Schinazi and Liotta testified at the Hearing. While Pharmasset submitted declarations from Drs. Choi, Lee, and Hong, the Panel declined to consider these written statements.

which led to the '065 patent was filed on March 8, 2004,[4] and it additionally claims priority to two Provisional Applications, the earliest of which was filed on February 25, 1998. The '083 application is a continuation of the '065 patent, and was filed by Claimants one day before they filed their Demand in this case (on July 27, 2009). The specifications of the '065 patent and the '083 patent are identical. The claims-at-issue are all method claims, the broadest scope of which is defined by claim 1 of the '065 patent:

> A method for the treatment of a HCV [hepatitis C virus] in a host in need thereof comprising administering an effective treatment amount of a β-D-2'-fluoronucleoside, or a pharmaceutically acceptable salt or prodrug thereof, optionally in a pharmaceutically acceptable carrier or diluent.

The dependent claims-at-issue specify additional limitations directed to the inclusion of particular types of bases.[5]

Unlike the '065 patent claims-at-issue, those of the '083 application include an additional limitation specifying that 2'-fluorine must be in the "α" or "down" stereochemical configuration.

B. Hepatitis C Virus

HCV is a positive-stranded RNA virus of the family Flaviviridae that infects humans and chimpanzees. HCV was first isolated and cloned in 1989,[6] though it had previously been identified as the "major causative agent for post-transfusion and for sporadic non-A, non-B hepatitis."[7] Replication of HCV occurs in part as a result of the enzymatic activity of a nonstructural protein present in HCV called HCV polymerase (also known as HCV NS5B RNA-dependent RNA-polymerase ("NS5B")). NS5B recognizes and binds to specific nucleotides and

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[4] The application which led to the '065 patent was filed roughly two months after the effective date of the Agreement.

[5] As discussed elsewhere in this Award, Claimants abandoned their contentions based on Pharmasset compounds with purine bases, and as such, claim 9 of the '065 patent and claim 56 of the '083 patent are not asserted by Claimants. In addition, to the extent that PSI-6130 and R7128 are the only compounds-at-issue, then because these compounds both have cytosine as the base, claim 5 and claim 52 of the '083 patent are likewise no longer being asserted by Claimants. The Panel's analysis regarding whether the specification adequately enables and/or provides sufficient written description of the remaining claims applies equally to all of the claims that have been at issue at any time in this arbitration.

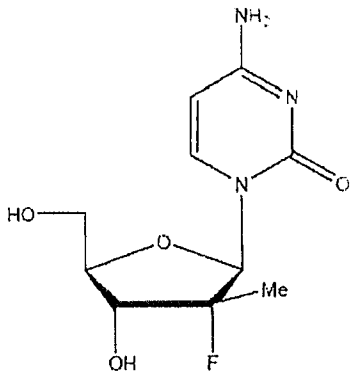
[6] *See, e.g.*, Tr. 356.

[7] JX-01 at Col. 2:55–58.

incorporates them into new strands of RNA that NS5B constructs. The RNA-dependent RNA-polymerase activity of NS5B was first reported in 1996.[8]

C. The Compounds-At-Issue

In their Post-Hearing Brief, Claimants contend that they are entitled to share in payments from Roche related to two compounds: PSI-6130 and R7128.[9] (Cl. Post-Hearing Br. at 1.) PSI-6130 is a synthetic compound which was first conceived of and made by then-Pharmasset-employee Jeremy Clark in the 2002-2003 timeframe.[10] PSI-6130 is the subject of U.S. Patent No. 7,429,572 ("the '572 patent"), entitled "Modified Fluorinated Nucleoside Analogues."[11] The '572 patent names Dr. Clark as the sole inventor, and claims priority to a provisional application dated May 30, 2003. PSI-6130 has the following chemical structure:



6130

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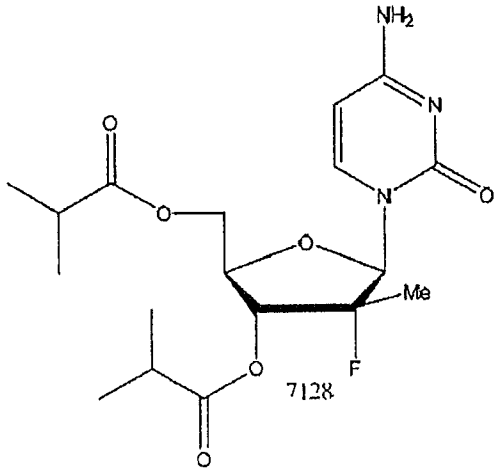
[8] *See* JX-26; Tr. 463.

[9] At the Hearing, Claimants contended that a number of compounds other than PSI-6130 and R7128 infringe the claims of the '065 patent and/or '083 application, including PSI-7851, PSI-7977, PSI-938, PSI-879, and PSI-661. (*See* Tr. 389–412.) However, Claimants appear to have dropped their contentions relating to these other compounds subsequent to the Hearing, and therefore the Panel does not address them. Were the panel to do so, however, the result reached would still be the same.

[10] *See, e.g.*, Tr. 283:10–285:10, 289:18–291:11, 788:5 -789:12; JX-38.

[11] *See* JX-49 at claim 1.

(PX-572.) R7128 is a prodrug of parent molecule PSI-6130,[12] and is synthesized directly from PSI-6130.[13] R7128 undergoes biotransformation to the active form of the parent molecule (PSI-6130-TP) in a host.[14] The chemical structure of R7128 is shown below:



(PX-572.) Clinical trials involving PSI-6130 and R7128 have shown effectiveness in treating HCV infection.[15]

ANALYSIS

The Agreement defines Licensed Products as "any process, service, or product involving the manufacture, use, sale, or import of one or more compounds within the Licensed Compound Series which is covered by a Valid Claim or incorporates or uses any Licensed Technology." (JX-2, Art. 1.11.) In order for Pharmasset to be liable for payments under the Agreement, (i) Pharmasset's (or Roche's) use of the Pharmasset compounds PSI-6130 and R7128 must be covered by a Valid Claim and (ii) the Pharmasset compounds PSI-6130 and R7128 must fall within the Licensed Compound Series.[16] Because Pharmasset has proven by clear and

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[12] CX-1217 (noting that R7128 is a prodrug of PSI-6130).

[13] CX-1276.

[14] CX-1256.

[15] *See* CX-1216; CX-1220; CX-1264.

[16] Alternatively, Pharmasset would be liable for payments under the Agreement if PSI-6130 or its prodrug were found to "incorporate[] or use[] any Licensed Technology," which is defined as "all formulations, designs, technical information, know-how, knowledge, data, specifications, test results and other information, whether or *(cont'd)*

convincing evidence that the asserted claims are invalid (or, in the case of the asserted claims of the '083 application, unpatentable) for failure to comply with the enablement and written description requirements of 35 U.S.C. § 112, ¶ 1, and because Claimants have failed to prove by a preponderance of the evidence that PSI-6130 or R7128 fall within the Licensed Compound Series, the Panel finds that neither Pharmasset nor Roche has made, used, or sold Licensed Products. Based on this finding, the Panel concludes that Claimants are not entitled under the Agreement to payments from Pharmasset for PSI-6130 or R7128.

Because the Panel has determined that PSI-6130 and R7128 are not Licensed Products, Pharmasset has failed to identify a Lead Candidate as required by Article 3.2(a) of the Agreement. This failure is a material breach of the Agreement, and therefore Claimants are entitled to terminate the Agreement pursuant to Article 12.2. The Panel further finds that while Pharmasset failed to provide required progress reports under the Agreement, this failure does not constitute a material breach.

Pharmasset also alleged that Claimants breached the Agreement by failing to notify Pharmasset in advance of the filing of the '083 application. The Panel finds that while Pharmasset should have been informed of and given the opportunity to advise before the filing of the '083 application, Claimants' failure to provide such notice does not constitute a material breach of the Agreement.

In light of the Panel's findings and interpretation of Article 14 of the Agreement, Claimants must reimburse Pharmasset for any AAA administrative fees, the costs of hearing facilities, and the Panel's travel expenses.

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not patented or patentable, which are known to the Inventors on the date of the License Agreement and are useful for the development, manufacture, use, commercialization, or sale of any Licensed Product." (JX-2, Art. 1.12.) The Panel finds that Claimants failed to establish that Licensed Technology relevant to the development of PSI-6130 or its prodrug was transferred from Claimants to Pharmasset under the Agreement. Indeed, the Panel notes that Claimants stated that they "are not focusing on Licensed Technology" as part of their claims for relief. (Claimants' Post-Hearing Brief, at 6 n.1.)

I. PHARMASSET HAS PROVEN BY CLEAR AND CONVINCING EVIDENCE THAT THE ASSERTED CLAIMS ARE INVALID/UNPATENTABLE[17]

A. Claim Construction

A Valid Claim is defined in the Agreement as "a claim included among the Licensed Patents so long as such claim shall not have been irrevocably abandoned or held invalid in an unappealable decision of a court or other authority of competent jurisdiction."[18] (Art. 1.19.) In order to determine whether the claims-at-issue should be "held invalid," as Pharmasset has argued, the Panel must first determine the scope of those claims. To that end, the parties jointly requested that the Panel construe certain disputed claim terms from the asserted patents during the discovery phase of this arbitration.

In accordance with the parties' request, the Panel held a claim construction hearing at the AAA offices in Atlanta on April 15, 2010. In addition to considering the oral arguments and written materials from this hearing, the Panel carefully considered all the parties' submissions regarding claim construction, including Claimants' Demand for Arbitration and Relief, Pharmasset's Answering Statement, Affirmative Defenses and Counterclaims, Claimants' Reply to Counterclaims and Affirmative Defenses, the parties' claim construction briefs and all relevant exhibits submitted therewith, as well as all applicable U.S. law. Having fully examined and analyzed this material, the Panel adopted the claim constructions detailed below.

The parties agreed upon the constructions of certain claim terms that appear in the asserted patents. In accordance with the parties' agreement, and as discussed at the claim construction hearing, the Panel adopted the following constructions for these terms:

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[17] In a written order dated October 28, 2010, the Panel first communicated its conclusion that the specification of the '065 patent and the '083 application fails to satisfy the enablement and the written description requirements of 35 U.S.C. § 112, and that therefore none of the claims-at-issue is valid/patentable. This Award explains the basic reasons for this determination. In that October 28th order, the Panel indicated that it would not address Pharmasset's other invalidity arguments (anticipation and obviousness under 35 U.S.C. §§ 102 and 103) in this Award unless one of the parties requested that the Panel do so. None of the parties made such a request, and therefore, the Panel's discussion of the validity/patentability of the asserted claims is limited to whether the specification-at-issue satisfies the requirements of 35 U.S.C. § 112, ¶ 1.

[18] There is no dispute that the '065 patent and the '083 application are Licensed Patents.

CLAIM TERM	AGREED CONSTRUCTION
a host in need thereof	a mammal that is infected with HCV
administering	to give or apply
HCV infection	an infection by the hepatitis C virus
effective treatment amount	an amount of a pharmaceutical ingredient given to a host that interferes with the proliferation and/or infectivity of HCV
wherein the 2'-fluoro of the β-D-2'-fluoronucleoside is alpha (α)	the 2'-fluoro of the nucleoside sugar has an alpha- (α-) orientation
purine base	A base with a fused 5,6-bicyclic heteroaromatic ring system that can be substituted with additional atoms.

The parties offered competing constructions for two terms: (i) β-D-2'-fluoronucleoside; and (ii) prodrug. After carefully considering all relevant evidence, the Panel adopted the following definitions:[19]

TERM	PANEL CONSTRUCTION
β-D-2'-fluoronucleoside	A compound comprising a D-sugar molecule having at least a fluorine at the 2' position. The D-sugar is bound to a heterocyclic base through a glycosyl bond having a beta- (β-) orientation, where the sugar and/or base may be natural or synthetic
Prodrug	A form of a parent molecule used in a transient manner to alter or eliminate undesirable properties in the parent molecule, and which form undergoes biotransformation before exhibiting its pharmacological effects.

The parties' principal claim construction dispute concerned the scope of the term β-D-2'-fluoronucleoside. Pharmasset's proposed definition was more limited than Claimants' definition (which, as indicated above, the Panel adopted). In contrast to Claimants' proposed definition,

[19] As part of its claim construction evaluation and decision, the Panel expressly noted that it had not considered the merits of any defense of patent invalidity under 35 U.S.C. § 101, 102, 103, or 112.

Pharmasset proposed that a β-D-2'-fluoronucleoside would be defined as only those compounds with a single fluorine substituent at the 2'-position. This definition would have excluded compounds with di-substitutions at the 2'-position (such as those with a fluorine and a methyl group), and would also have resulted in claims of much more limited scope.

B. The Specification of the Patents-At-Issue Does Not Enable The Asserted Claims

1. The Enablement Standard

Under Section 112 of the Patent Act, the specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms *as to enable any person skilled in the art* to which it pertains, or with which it is most nearly connected, *to make and use the same.*" 35 U.S.C. § 112 (emphasis added). A patent claim is invalid for lack of enablement if the written description fails to teach a person of ordinary skill in the art to make and use the invention as broadly as it is claimed without undue experimentation. *See, e.g., Alza Corp. v. Andrx Pharmaceuticals,* 603 F.3d 935, 940 (Fed. Cir. 2010); *In re Cortright,* 165 F.3d 1353, 1356 (Fed. Cir. 1999).

The specification must enable one of ordinary skill in the art to practice "the full scope of the claimed invention." *Chiron Corp. v. Genetech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004) (*citing In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). "[A]s part of the quid pro quo of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (stating further that "when a range is claimed, there must be reasonable enablement of the scope of the range").

In determining what constitutes undue experimentation, the Federal Circuit applies a test that is not merely quantitative, but which also qualitatively assesses the art and claims at issue. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Factors that should be considered in such evaluation include, but are not limited to: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) level of one of ordinary skill; (5) level of predictability in the art; (6) amount of direction provided by the inventor; (7) existence of working examples; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure. *Id.*

Two factors—"level of predictability in the art" and "breadth of the claims"—are inversely related. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the Federal Circuit has refused to find broad, generic claims enabled by specifications that describe few embodiments and that do not demonstrate with reasonable specificity how to make and use other embodiments within the full scope of the claim. *PPG*

Indus. v. Guardian Indus. Corp, 75 F.3d 1558 (Fed. Cir. 1996); *see also In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991).

2. Undue Experimentation Would Be Required To Enable A Person of Ordinary Skill in the Art To Practice The Asserted Claims

In order to practice the patented methods, a person of ordinary skill in the art must be able to (i) make the β-D-2'-fluoronucleosides (or a pharmaceutically acceptable salt or prodrug thereof) embraced by the asserted claims of the patents-at-issue and (ii) determine an effective amount of such compounds for the treatment of HCV. As of 1998, a person of ordinary skill in the art (defined below) would encounter significant challenges in performing both of these aspects of the patented methods, especially given the limited nature of the disclosure in the specification relating to HCV, and could do so only with undue experimentation.

(a) Level of Skill in the Art

The Panel finds that a person of ordinary skill in the art would possess the following credentials and/or experience, as of February 1998:[20]

- At least an M.S. degree in chemistry, organic chemistry, or medicinal chemistry;
- Several years of experience in the design, synthesis, and characterization of nucleosides for biological investigation, such that a person with an M.S. would have at least 4 years of experience, and a person with a Ph.D. would have at least 2 years of experience; and
- An understanding of antiviral target-oriented synthesis and testing, including a basic understanding of (i) viral drug targets and the enzymology of those targets; (ii) structure activity relationships (known as "SAR"); and (iii) drug pharmacology and metabolism.

The person of "ordinary" skill in this particular field is therefore a highly skilled individual, versed in both principles and practices of synthetic organic chemistry and associated virology.

(b) Breadth of the Claims

As noted above, the Panel adopted Claimants' proposed construction for the term β-D-2'-fluoronucleoside. Pharmasset contends that under this construction, more than 262

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[20] There is no dispute among the parties that the validity of the patents-at-issue is assessed based upon the knowledge of a person of skill in the art as of February 1998.

quadrillion compounds fall within the class of compounds claimed in the patents-at-issue.[21] Claimants have disputed this figure, arguing that the person of ordinary skill in the art would understand that, as a practical matter, the claims are limited to a "small" number of compounds with particular types of substitutions.[22]

The Panel need not determine with precision the exact number of β-D-2'-fluoronucleoside compounds which fall within the scope of the claims-at-issue. The Panel concludes that the number is neither as limited as Claimants suggest, nor as expansive as Pharmasset contends. Suffice it to say, the Panel is convinced that these claims encompass a very large number of nucleoside compounds that have "at least a fluorine at the 2'-position," and that this number supports its conclusion that the specification lacks proper enablement (and written description) under 35 U.S.C. § 112, ¶ 1.

In a number of cases involving broad generic claims, albeit of more limited scope than those at issue here, the Federal Circuit affirmed district court holdings that such claims were invalid for lack of enablement.

For instance, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991) the Federal Circuit affirmed the invalidity of a generic claim of United States Patent No. 4,703,008, directed to "all possible DNA sequences that will encode any polypeptide having an amino acid sequence 'sufficiently duplicative' of EPO to possess the property of increasing production of red blood cells." *Id.* at 1212. In affirming the district court's invalidity finding, the Court noted that the asserted claim was extremely broad: "[O]ver 3,600 different EPO analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids." *Id.* at 1213.

In a similar fashion, the claims-at-issue here are directed to methods involving millions of β-D-2'-fluoronucleoside compounds. In order to enable such a broad claim, the disclosure must be commensurate with its entire scope. *See, e.g., Alza,* 603 F.3d at 942 (noting Alza successfully argued for a claim scope it had failed to enable); *Pharm. Resources, Inc. v. Roxane Labs., Inc.*, 253 Fed. App'x 26, 30 (Fed. Cir. 2007). Given this precedent, the breadth of the claims-at-issue poses a serious challenge to satisfying the enablement standard.

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[21] *See, e.g.*, Pharmasset's Combined Memorandum in Support of Its Motions for Summary Judgment of Invalidity, at 20–21; Tr. 976:1–978:7.

[22] Tr. 1445:11-1446:15.

(c) The Unpredictable Nature of the Invention and Art, Lack of Guidance, Lack of Working Examples, and Nascent State of the Art Weigh Strongly Against a Finding of Enablement

The fields of chemical synthesis, virology, and physiology have long been recognized as unpredictable. *See, e.g., In re Fisher*, 427 F.2d 833, 838-39, (C.C.P.A. 1970) ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."); *accord In re Bowen*, 492 F.2d 859, 861-64 (C.C.P.A. 1974); *Singh v. Brake*, 317 F.3d 1334, 1344 (Fed. Cir. 2003) (noting that "replacing a functional group on a chemical compound can often have highly unpredictable results").

Generally speaking, there is no question that the claims-at-issue concern a highly unpredictable field.[23] But aside from this general unpredictability, the particular subject matter of the claims-at-issue—the use of synthetic β-D-2'-fluoronucleosides to effectively treat a host infected with HCV—is highly unpredictable. Even the highly skilled artisan working in this field would have required substantial guidance to synthesize β-D-2'-fluoronucleosides and assess their effectiveness against HCV, including their toxic effects on the host. Each of these actions involves considerable unpredictability—and the specification fails to provide adequate guidance to allow a person of ordinary skill in the art to perform them, absent significant and undue experimentation.

Synthesis. The design and synthesis of a β-D-2'-fluoronucleoside are complex, uncertain and experimental in nature.[24] While it is easier to design and carry out a synthetic method when the particular, desired end-product is already known,[25] the enablement inquiry is not based on any such "reverse engineering," but rather is directed to the full scope of the claim.

The specification discloses a number of synthetic schemes, but all are directed to obtaining monofluorinated compounds, many of which are in the "L" configuration (rather than the D configuration, as required by the claims at issue).[26] Moreover, all end-products discussed

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[23] Claimants' witness, Dr. Schinazi, acknowledged that the activity of the fluoronucleoside compounds cannot be predicted from their structure. (Tr. 286:15-17; 291:12-292:7.) Likewise, Claimants' expert, Dr. Kane, opined that one could not tell whether a compound, such as PSI-6130, would inhibit NS5B HCV polymerase without testing it. (Tr. 513:2-518:6.)

[24] Tr. 993:24–994:18.

[25] *Id.*

[26] *See* JX-1 at Col. 20–29.

and depicted lack a hydroxyl group in the 3'-position.[27] Indeed, the only specific compound identified in the specification with a disubstituted 2'-carbon in the sugar ring is an intermediate in Scheme 7, a synthetic scheme leading to a product with a double bond between the 2' and 3'-positions. The specification does highlight two different ways of introducing a fluorine atom into the sugar ring: (i) through nucleophilic attack on an anhydro-nucleoside; and (ii) through replacement and inversion of a stereochemically fixed hydroxyl group with diethylaminosulfur trifluoride (DAST).[28] While it is true that Pharmasset ultimately used a form of the DAST method to synthesize PSI-6130 and R7130,[29] there is insufficient evidence that a person of ordinary skill in the art could have used this method to synthesize these compounds (or any other disubstituted fluorinated nucleoside, particularly ones having a hetero-substitution at the 2'-position) as of February 1998.

Anti-HCV Activity. As discussed above, RNA-dependent RNA-polymerase NS5B is required for HCV replication. Inhibiting NS5B therefore presents an attractive therapeutic target for HCV treatment. A compound can interfere with HCV replication if (i) NS5B recognizes the compound; (ii) NS5B incorporates the compound into the RNA strand being replicated; and (iii) once incorporated, the compound interferes with the functionality of the HCV virus.[30] The '065 patent provides no guidance regarding how to determine which β-D-2'-fluoronucleosides inhibit NS5B activity/HCV replication, and the evidence demonstrates that the effects of β-D-2'-fluoronucleosides are highly unpredictable.[31]

The specification provides only that "[c]ompounds can exhibit anti-hepatitis C activity by inhibiting HCV polymerase, by inhibiting other enzymes needed in the replication cycle, or by other known methods."[32] The specification does not identify any particular β-D-2'-fluoronucleosides that exhibit such activity, how this inhibition occurs, or the particular

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[27] Claimants' witness, Dr. Liotta, explained that the 3'-hydroxyl moiety is critical to the successful treatment of HCV. (Tr. 152:25-153:24.)

[28] *Id.* at Col. 24:39–43.

[29] *See, e.g.*, Tr. 1437:19–1438:5.

[30] *See* Tr. 990:15–992:13.

[31] For instance, while 2'-fluoro-cytidine shows significant anti-HCV activity, 2'-fluro-uridine is completely inactive, showing no anti-HCV effects in the replicon assay. A similar decrease in anti-HCV effects is observed when the stereochemistry of PSI-6130 is altered. (Tr. 1285:16–1286:12.)

[32] JX-1 at Col. 61:65–62:1.

polymerase that should be the target of the inhibitory activity.[33] The patents-at-issue contain no evidence that the patentees ever tested a single β-D-2'-fluoronucleoside for anti-HCV-activity; indeed, the only testing data provided in the specification relate to the effectiveness of L-nucleosides against HIV.[34]

It is not surprising that there is no testing data regarding anti-HCV-activity, because it appears that there was no adequate test to screen for anti-HCV-activity of a nucleoside as of February 1998. The specification discloses two methods, which have generally been referred to as Hagedorn 1996 and Bartholomeusz during the course of this arbitration, and which were allegedly available to "assess [anti-HCV] activity."[35] In addition, the parties introduced evidence and testimony regarding two other assays, referred to as Behrens 1996 and Lohmann 1997.

The Panel finds that just because there were publications discussing early attempts at assaying anti-HCV-activity, that does not mean that the field had developed sufficiently that a person of ordinary skill could practice the full scope of the invention. At the time, these assays were cutting-edge technology, which needed further verification, development, and optimization before they could be used by a person of ordinary skill in the art to assess anti-HCV-activity in practice. Indeed, there were serious questions about the reproducibility of these early studies, as well as whether the activity of the HCV polymerase was sufficiently robust to permit functional screening methods to be developed from these original studies.[36] While these early studies may have been (and, in fact, ultimately were) developed into practical assays for assessing anti-HCV activity, this aspect of the art was in its infancy as of February 1998, such that, even if the highly skilled artisan had been armed with the available references, significant additional experimentation would have been necessary to develop a reliable screening assay that would have allowed the claimed method to be practiced.[37]

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[33] The unpredictability inherent in this field is exacerbated by the fact that nearly identical β-D-2'-fluoronucleosides have been shown to have dramatically different anti-HCV activity. (*See, e.g.* PX-630.)

[34] *Id.* at Col. 47:1–24. A person of ordinary skill in the art would be unable to extrapolate any meaningful information about anti-HCV activity from the data regarding anti-HIV activity provided in the '065 patent specification. *See* Tr. 962:8–17.

[35] JX-1 at Col. 62:1–14. There was no dispute that the Bartholomeusz reference would not be used by a person of ordinary skill in the art to assess anti-HCV activity. (Tr. 511:16–24.)

[36] *See, e.g.*, Tr. 1136:13–1137:9; 1158:4–1161:6.

[37] Indeed, the cell-based replicon assay that was later used by Pharmasset to assess anti-HCV activity was not available until after the filing date of the patents-at-issue. *See* Tr. 803:14–805:3.

Effective Treatment Amount/Toxicity.[38] Foreign nucleoside compounds that are introduced to target NS5B activity (and, as a result, to inhibit HCV replication) may be incorporated by the human cell itself and can be unduly toxic to the host. Thus, compounds with anti-HCV-activity may not provide an effective treatment for HCV, even though they inhibit HCV polymerase, particularly since they are often and unpredictably toxic. The Panel finds that considerable trial-and-error experimentation and testing would have been necessary to discover compounds that could be effectively administered to treat HCV without undue, off-target toxic side effects.

The specification discloses no testing data or working examples regarding the toxicity of β-D-2'-fluoronucleosides exhibiting anti-HCV-activity.[39] Moreover, Pharmasset's investigation into 2'-fluoronucleosides demonstrates that small changes in the chemical structure will result in wide and unpredictable swings in cytotoxicity. For instance, a nucleoside with a single methyl at the 2'-position exhibits significant cytotoxicity, while a similar compound with a single fluorine substitution exhibits similarly adverse off-target toxicity.[40] The same is true for 2'-fluoro-deoxy-cytidine (referred to during the course of this arbitration as "2FdC").[41] Yet, PSI-6130, which is structurally similar to all three of these compounds, demonstrates toxicity which is several orders of magnitude less than that observed from the other compounds. Given this lack of predictability, substantial guidance would have been necessary to enable a person of ordinary skill in the art to practice the claimed method. None is provided in the specification.

In arguing that the enablement requirement is satisfied in this case, Claimants rely heavily on what one of skill in the art would have known and have been able to do in February 1998, rather than what is actually disclosed in the specification. However, the Federal Circuit

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[38] During the course of the arbitration, Claimants' expert, Dr. Radtke, suggested that based upon the Panel's construction of the undisputed term "effective treatment amount," it is not necessary to consider the toxicity of a given β-D-2'-fluoronucleoside, so long as it shows anti-HCV activity. (Tr. 1536:15–1541:22.) The Panel notes that its construction of this term must be read within the context of the entire claim, which is directed towards *effectively* treating HCV infection in a host, and as such, assessing the toxicity of a given β-D-2'-fluoronucleoside is an essential part of practicing the claimed method. In fact, Dr. Radtke's Claim Construction Report confirms the Panel's determination in this regard, noting that "one of ordinary skill in the art would understand that a drug that shows promise during clinical development may not live up to its potential upon administration to patients. Obstacles to efficacy include, but are not limited to . . . toxicity." (Radtke Claim Const. Rep., ¶ 42.)

[39] *See, e.g.*, Tr. 217:4–16; 226:17–21.

[40] *See, e.g.*, PX-630.

[41] Tr. 912:5–913:6.

has repeatedly emphasized that while the specification "need not disclose what is well known in the art," this rule is "merely a rule of supplementation, not a substitute for a basic enabling disclosure.'" *Alza*, 603 F. 3d at 940–41 (internal quotations and citations omitted). As such, a patentee is "required to provide an adequate enabling disclosure in the specification; it cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *Id.* at 941 (citations omitted). The same analysis applies here.

3. Conclusion—Lack of Enablement

The claimed invention is directed to a method of effectively treating a disease that was not isolated or characterized until April of 1989, using a voluminous class of compounds with unpredictable effects, to target a protein whose activity was not discovered until 1996, and which requires the use of screening and toxicity assays that were either in their infancy or that were unavailable as of February 1998. The disclosure of the patents-in-suit thus provided an inadequate disclosure of (i) how to synthesize β-D-2'-fluoronucleoside compounds, including those with hetero-substitutions with the claimed stereochemistry at the 2'-position while maintaining a hydroxyl group at the 3'-position; (ii) how to assess the effectiveness of any β-D-2'-fluoronucleoside against HCV activity; or (iii) how to predict and determine the toxicity of a given β-D-2'-fluoronucleoside compound so as to determine an effective treatment amount. Although the level of skill in the relevant art is high, all of the other *Wands* factors weigh strongly against a finding of enablement. Therefore, the Panel finds that Pharmasset has proven by clear and convincing evidence that the specification fails to permit a person of ordinary skill in the art to practice the full scope of the claims-at-issue absent undue experimentation within the meaning of 35 U.S.C. § 112, ¶ 1.

C. The Specification Fails to Satisfy the Written Description Requirement

1. Written Description Standard

Sitting *en banc*, the Federal Circuit recently considered the nature of the written description requirement, and concluded that the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 98 F.3d 1336, 1351 (Fed. Cir. 2010) (citations omitted). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor *had possession of the claimed subject matter* as of the filing date." *Id.* (emphasis added). Applying this standard, the Panel finds that Pharmasset has proven by clear and convincing evidence that the patentees did not have possession of the claimed methods as of February 1998.

2. Failure to Provide Adequate Written Description

Only a few portions of an otherwise lengthy specification discuss HCV, none of which demonstrates that the inventors had possession of a method of treating HCV using an effective treatment amount of a β-D-2'-fluoronucleoside. In fact, the entirety of the HCV teachings are contained in the following two excerpts, which are directed primarily to a recitation of known teachings from the prior art:

> Hepatitis C virus ("HCV") is the major causative agent for post-transfusion and for sporadic non A, non B hepatitis (Alter, H. J. (1990) *J. Gastro. Hepatol.* 1:78-94; Dienstag, J. L. (1983) *Gastro* 85:439-462). Despite improved screening, HCV still accounts for at least 25% of the acute viral hepatitis in many countries (Alter, H. J. (1990) supra, Dienstag, J. L. (1983) supra; Alter M. J. et al. (1990a) *J.A.M.A.* 264:2231-2235, Alter M. J. et al (1992) *N. Engl. J. Med.* 327:1899-1905; Alter, M. J. et al. (1990b) *N. Engl. J. Med.* 321:1494-1500). Infection by HCV is insidious in a high proportion of chronically infected (and infectious) carriers who may not experience clinical symptoms for many years. The high rate of progression of acute infection to chronic infection (70-100%) and liver disease (>50%), its world-wide distribution and lack of a vaccine make HCV a significant cause of morbidity and mortality.
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> VI. Anti-Hepatitis C Activity
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> Compounds can exhibit anti-hepatitis C activity by inhibiting HCV polymerase, by inhibiting other enzymes needed
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> in the replication cycle, or by other known methods. A number of assays have been published to assess these activities
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> WO 97/12033, filed on Sep. 27, 1996, by Emory University, listing C. Hagedorn and A. Reinoldus as inventors, and which claims priority to U.S. Ser. No. 60/004,383, filed on September 1995, describes an HCV polymerase assay that can be used to evaluate the activity of the compounds described herein. This application and invention is exclusively licensed to Triangle Pharmaceuticals, Inc., Durham, N.C. Another HCV polymerase assays has been reported by Bartholomeusz, et al., Hepatitis C virus (HCV) RNA polymerase assay using cloned HCV non-structural proteins; Antiviral Therapy 1996:1(Supp 4) 18-24.

(JX-1, Col. 2:55–3:3; 61:65–62:14.) This limited disclosure is dwarfed by other topics addressed at length in the specification, including for example the preparation of L-2'-fluoro-2',3'-unsaturated nucleosides (JX-1, col. 36:41–47:23); anti-HIV-activity (col. 59:42–61:9); and treatment of abnormal cellular proliferation (col. 62:16–63:39).

The specification contains no testing data relating to HCV, no working examples or testing data of any β-D-2'-fluoronucleoside against any virus, and no testing data regarding the toxicity or off-target effects of any β-D-2'-fluoronucleoside.[42] As noted in the preceding paragraph, the patent does contain disclosure relating to the effectiveness of certain compounds against certain types of viruses, including HIV and HBV. For instance, the patentee provided information regarding cytotoxicity and antiviral testing data for certain 2'-fluoronucleosides against HIV, but no such data are provided for HCV. The patentee's failure to provide such data for HCV while doing so for other viruses supports the Panel's conclusion that the patentee was not in possession of any method for effectively treating HCV with any β-D-2'-fluoronucleoside as of February 1998.

Recently, the Federal Circuit has twice held similar biochemical patents invalid for lack of adequate written description. *Ariad Pharms., Inc.*, 598 F.3d at 1336; *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). In each case, the Court noted the outcome-determinative distinction between a proposition that compounds *might* be useful as a treatment and the actual disclosure of compounds that have the claimed utility. In *Ariad*, the Federal Circuit highlighted that:

> Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.

Ariad, 598 F.3d at 1353 (internal citations omitted).

Likewise, in *University of Rochester*, the Federal Circuit held that a biochemical patent similar to that at issue here was invalid for lack of written description. The specification disclosed the idea that inhibition of mammalian prostaglandin H synthase-2 ("PGHS-2") could result in reduced side effects common from the use of non-steroidal anti-inflammatory drugs ("NSAIDs") and a screening assay to test whether a compound selectively inhibits PGHS-2. *Id.* Like the patents-at-issue here, the *University of Rochester* patent contained no data revealing a compound with the desired biological activity. The Federal Circuit reiterated the concerns of the district court:

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[42] *See* JX-1; *see also* Tr. 1483:1–1485:4.

> Tellingly, . . . what plaintiff's experts'[sic] do not say is that one of skill in the art would, from reading the patent, understand what compound or compounds – which, as the patent makes clear, are necessary to practice the claimed method – would be suitable, nor would one know how to find such a compound except through trial and error. . . . Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method – a compound that selectively inhibits PGHS-2 activity – was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Id. at 925-26 (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216, 229 (W.D.N.Y. 2003)).

This case is similar to *Ariad* and *Rochester*. Like the patentees in those cases, the inventors of the patents-at-issue provided no working examples or testing data for any of the claimed methods, and thus the patentees were merely suggesting a number of possible solutions to the challenge of treating HCV infection. As Claimants' expert acknowledged at the hearing, the patents-at-issue provide merely a "plan" for identifying potential treatments against HCV.[43] Under the standard articulated by the Federal Circuit, providing the mere starting point for research into methods for effectively treating HCV with a β-D-2'-fluoronucleoside, as Claimants have done here, is inadequate to show possession of the claimed method, and therefore fails to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1.

II. CLAIMANTS HAVE FAILED TO PROVE THAT THE ACCUSED COMPOUNDS FALL WITHIN THE LICENSED COMPOUND SERIES

The Panel's conclusion in Section I does not fully resolve whether Pharmasset still may be liable for payments under the Agreement. The definition of "Valid Claim" in the Agreement provides that pending and issued claims must be treated as valid unless or until they are finally determined to be invalid, which did not occur until the Panel issued its ruling on October 28, 2010.[44] As such, Claimants contend that Pharmasset is liable for a variety of

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[43] Tr. 1482:18-1483:14.

[44] As Pharmasset points out, there is some question under Federal Circuit law whether (even with the express contractual provision providing for royalty payments until a claim is declared invalid) Claimants should be allowed to recover any allegedly unpaid royalties, or whether (assuming the use or sale of Licensed Products had occurred) Claimants could recover royalties up until Pharmasset first alleged that the '065 patent was invalid in this arbitration. *Cf. Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir. 1997); *Lear v. Adkins*, 395 U.S. 653 (1969). Because the Panel concludes that neither PSI-6150 nor R7128 is within the Licensed Compound Series, this issue is moot.

payments associated with PSI-6150 and R7128 up until the Panel formally declared the claims-at-issue to be invalid. However, because the Panel finds that neither of these compounds is within the Licensed Compound Series, Pharmasset is not liable for any payments associated with their use or development.

Under paragraph 1.9 of the Agreement, Licensed Compound Series is defined as "all 2'-Fluoronucleosides and their pharmaceutically acceptable salts, polymorphs, N-alkylated derivatives and 5'-phosphate pro-drugs, and all geometric and/or optical isomers thereof that are enabled in the Licensed Patents." There is no dispute that PSI-6130 is a 2'-fluoronucleoside, and that R7128 is a 5'-phosphate pro-drug of PSI-6130. Thus, the Panel must determine (i) whether the definition of Licensed Compound Series requires these compounds to be "enabled in the Licensed Patents," and (ii) if so, whether PSI-6130 and R7128 are enabled by the specification.[45]

The parties have disputed whether the phrase "that are enabled in the Licensed Patents" modifies all of the language in the definition that precedes it, or whether it modifies only the portion of the preceding definition that refers to "all geometric and/or optical isomers thereof." The Panel does not accept Claimant's argument that this language of the Agreement is unambiguous or that it has a plain and ordinary meaning in the context of the Agreement.[46] However, after considering the relevant evidence offered by the parties,[47] and reviewing the overall structure and purpose of the Agreement, the Panel finds that the phrase "that are enabled in the Licensed Patents" modifies all of the preceding language in the definition of Licensed Compound Series. The Panel further concludes that the phrase "that are enabled in the Licensed Patents" should be measured by the enablement standard codified in 35 U.S.C. § 112. Therefore, Claimants had the burden to prove by the preponderance of the evidence that PSI-6130 and R7128 are enabled by the specification. Indeed, the Panel notes that even if it had agreed with Claimants' proposed interpretation, Claimants would still have had this same burden, because PSI-6130 and R7128 are indisputably "geometric and/or optical isomers" of a 2'-fluoronucleoside.[48]

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[45] Although the Panel has determined that the specification is inadequate to enable a person of skill in the art to make and use the full scope of the claimed invention, that is a different inquiry from whether only PSI-6130 and R7128 are enabled by the specification.

[46] *See, e.g.* Claimants' Post-Hearing Br. at 9–10.

[47] There is no dispute that this language was added to a draft of the Agreement on August 29, 2003, by John DesRosier, a consultant acting on behalf of UGARF. (Tr. 1347:12–1349:2; PX-545.) Mr. DesRosier did not appear at the Hearing, either in person or by deposition.

[48] Tr. 181:23 182:4; 214:9–215:20; 296:7–24; 297:10–21.

The question before the Panel is thus whether Claimants have established that the specification would have enabled a person of ordinary skill in the art (as defined *supra*) to make and use PSI-6130 and R7128 without undue experimentation. The Panel concludes that a person of ordinary skill could not have made these compounds prior to February 1998 without significant and time-consuming experimental efforts. The only synthetic schemes disclosed in the specification are directed to making mono-fluorinated compounds, do not suggest the presence of both a methyl group and a fluorine at the 2'-position, and do not describe how to maintain or provide a hydroxyl group at the 3'-position while fluorinating and methylating the 2'-position. Indeed, persons of skill in the art have encountered great difficulty as recently as 2009 when trying to synthesize a methylated 2'-fluoronucleoside with a hydroxyl at the 3'-position, because that hydroxyl group is typically eliminated during the synthetic process.[49] And while then-Pharmasset-employee Dr. Clark was able to synthesize PSI-6130 using a version of the DAST method in 2002/2003, this fact does not inform whether the DAST method known in 1998 combined with the limited disclosure of the specification would have enabled such a synthesis.

In any event, even if a person of ordinary skill in the art would have been able to make these compounds prior to February 1998 without undue experimentation, the Panel finds that their effective use against HCV infection would not have been enabled by the Licensed Patents at issue by that date. As discussed above, the enablement requirement involves more than merely outlining a "plan" or hypothesis that certain members of a broad class of compounds may be useful anti-viral agents. Neither the specification nor the prior art at issue supports the conclusion that a person of ordinary skill in the art would have been able to screen or test for anti-HCV activity (specifically inhibiting NS5B),[50] assess the cytotoxic effects of PSI-6130 and R7128, and balance these considerations to develop an effective treatment amount for a host, without significant and lengthy trial-and-error experimentation prior to February 1998.[51]

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[49] *See, e.g.*, JX-39.

[50] Pharmasset's experts testified that if PSI-6130 were tested in the enzyme assays available in 1998, it would not show activity against the NS5B HCV polymerase, at least unless first converted into the triphosphate form. (Tr. 1185:6-1186:4; 1304:19-1306:18.) Claimants' expert, Dr. Kane, similarly noted that PSI-6130 would likely need to be converted to the triphosphate before it would show efficacy in the 1996 Behrens assay, and otherwise declined to predict whether PSI-6130 would show activity against NS5B HCV polymerase in the assays available as of the priority date. (Tr. 517:2-518:6.) The patent specification does not disclose the need for such a conversion.

[51] *See* Section I.B.2 for a discussion of the evidence and testimony supporting this conclusion.

III. CLAIMANTS ARE ENTITLED TO TERMINATE THE AGREEMENT

As outlined in Section II, the Panel finds that Claimants have not proven that either PSI-6130 or R7128 falls within the Licensed Compound Series. Claimants assert that if the Panel so found, Pharmasset breached its diligence obligations and the Universities are entitled to terminate the Agreement. Claimants did not seek damages for this alleged breach.[52] Article 3.2(a) of the Agreement requires Pharmasset to "identif[y] the first Lead Candidate within four (4) years of the Effective Date of [the] Agreement."[53] The term "Lead Candidate" is defined as "any compound within the Licensed Compound Series which has been developed to the Lead Candidate stage as described in LICENSEE's Development Plan (see EXHIBIT B)." To reach the "Lead Candidate stage" under the Agreement, a 2'-fluoronucleoside must produce satisfactory results in a number of pharmokinetic, toxicological, metabolic, and preclinical *in vivo* testing and validation studies.[54]

Claimants do not have the unfettered right to terminate the Agreement upon notice to Pharmasset; instead, the Agreement enumerates only certain events which trigger a right of termination. Those events include a lack of diligence as set forth in Article 3 and the breach of any other material term of this Agreement. (Agreement Art. 12.2(b); 12.2(h).)

Pharmasset has not identified any Lead Candidate to the Universities, and more than four years have passed since the effective date of the Agreement.[55] Therefore, the Panel finds that Pharmasset has failed to exhibit the diligence required by Article 3, and has materially breached the Agreement, giving Claimants the right to terminate under Article 12.2.

IV. CLAIMANTS HAVE NOT MATERIALLY BREACHED THE AGREEMENT

Pharmasset contends that Claimants breached the Agreement by failing to notify Pharmasset in advance of the filing of the '083 application. Under the Agreement, Claimants have an obligation to keep Pharmasset "informed as to all developments with respect to Licensed

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[52] Claimants' Post-Hearing Brief, at 38.

[53] Claimants' Demand for Arbitration and arguments at the Hearing indicate that Claimants were also seeking a declaration that Pharmasset's failure to comply with its reporting obligations constitutes a material breach of the Agreement. Claimants appear to have abandoned this argument in its Post-Hearing Brief. In any event, the Panel finds that, while Pharmasset failed to comply with its reporting obligations under Article 5.2 of the Agreement, this failure does not constitute a material breach.

[54] Agreement, Ex. B; Tr. 914:23–915:24.

[55] Tr. 900:13–19; 914:7–916:4.

Patents" and to allow Pharmasset "reasonable opportunities to advise . . . and cooperate . . . in [the] prosecution and maintenance" of Licensed Patents. (Agreement Art. 7.1.) The Panel finds that this provision of the Agreement requires that, so long as the Agreement has not been terminated by either party, Pharmasset be informed of and given the opportunity to advise before the filing of an application such as the '083 application, which Claimants failed to do.

However, the Panel finds that Claimants' failure to do so does not constitute a material breach of the Agreement. The Panel's finding in this regard is informed by the fact that Pharmasset, "upon ninety (90) days written notice to UNIVERSITIES, may advise UNIVERSITIES that it no longer wishes to pay expenses for filing, prosecuting or maintaining one or more Licensed Patents." At any time after it learned of the filing of the '083 application (which was on the day after it was filed), Pharmasset could have provided such written notice, which would have relieved it of any further financial obligations associated with the '083 application after 90 days. There is no evidence that Pharmasset has done so. There also is no evidence that Pharmasset provided Claimants with any advice concerning the '083 application after learning of its existence.[56] As such, the failure on the part of the Claimants to allow Pharmasset to advise regarding the '083 application before it was filed is tempered by the fact that Pharmasset took no affirmative steps under the Agreement to address the '083 application after it learned of the filing.

V. ALLOCATION OF FEES/EXPENSES

Article 14 of the Agreement provides that "the fees and expenses incurred in connection with . . . arbitration shall be borne by the party initiating the arbitration proceeding (or equally by both parties if both parties jointly initiate such proceeding) subject to reimbursement by the party which does not prevail." The Panel finds that this arbitration was initiated solely by Claimants, and that Pharmasset is the prevailing party in this arbitration.[57] Although Article 14 provides for the initiating party to bear the burden of initially paying "fees and expenses," the parties separately agreed to share in certain fees and expenses associated with the arbitration. Therefore, Pharmasset is entitled to be reimbursed for certain of those expenditures, and the Panel must determine what is meant by the phrase "fees and expenses."

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[56] *See, e.g.*, Tr. 1264:4–13.

[57] Although the Panel finds that Pharmasset is the prevailing party, the Panel also finds that the issues and arguments in this arbitration were credibly and competently presented by both sides, and that Claimants had a reasonable basis to assert that they were entitled to payments under the Agreement based upon at least PSI-6130 and R7128. As such, the Panel declines to award Pharmasset any fees, expenses, or costs other than those specifically identified in this Award pursuant to Article 14 of the Agreement.

The parties offered no testimony at the Hearing as to what is meant by the phrase "fees and expenses," and this phrase is not defined in the Agreement. Based upon its reading of the Agreement and the Commercial Rules of the American Arbitration Association, including in particular Rules 42, 49, and 51, the Panel finds that the phrase "fees and expenses" does not include any party's attorneys' fees, expert witness fees, costs for court reporters, photocopying, or expenses of document and e-discovery vendors, or compensation for the neutral arbitrator. As such, Claimants shall reimburse Pharmasset for its fees paid to the AAA, the cost of the hearing facilities, and the Panel's travel expenses. Other than these three categories, the parties shall respectively bear their own fees, expenses, costs, or other expenditures.

CONCLUSION

The Panel finds that Claimants have failed to prove by a preponderance of the evidence that Pharmasset or Roche made, developed, used, imported, offered for sale or sold any Licensed Products. This conclusion is based on two underlying findings. First, the Panel finds that Pharmasset has proven by clear and convincing evidence that the asserted claims of the Licensed Patents at issue are invalid and/or unpatentable under the first paragraph of 35 U.S.C. § 112 for failing to satisfy the written description and enablement requirements. As such, none of the Pharamsset compounds at issue nor their use is covered by a Valid Claim. Second, Claimants have not shown by a preponderance of the evidence that any of the Pharmasset compounds at issue are within the Licensed Compound Series. Therefore, Claimants' request for an award of damages is denied.

The Panel further finds that Pharmasset's failure to identify a Lead Candidate constitutes a material breach of the Agreement, such that Claimants' are entitled to terminate the Agreement pursuant to Article 12.2. Conversely, Claimants have not materially breached the Agreement by failing to notify Pharmasset before filing the '083 application.

Subject to a final accounting from the parties and the Panel members to be submitted no later than 14 days from the date of this Award, Claimants shall reimburse Pharmasset for (i) fees paid to the American Arbitration Association in the amount of $4,500.00; (ii) costs paid for the hearing facilities; and (iii) travel and accommodation expenses of the Panel.

This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. All claims not expressly granted herein are hereby denied.

This Award may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute together one and the same instrument.

The Panel leaves to the parties the filing of this Award with the Director of the U.S. Patent & Trademark Office pursuant to 35 U.S.C. § 294(d).

Dec 6, 2010
Date

Edward V. Filardi

Dec 3, 2010
Date

Rudolf E. Hutz

Dec. 3 2010
Date

Nancy J. Linck, Ph.D.